AMENDMENTS TO THE CLAIMS

Please cancel claims 49 and 50, add new claims 56-73, and amend claims 27, 31, 34, 38, 39, 40 and 48 as follows. The following listing of claims will replace all prior versions, and listings, of claims in the application:

Claims 1-26 (Cancelled).

27. (Currently Amended) A test device for determining the presence of a ligand in a liquid sample, the device comprising:

a test strip comprising a sorbent material which defines a flow path for transporting the liquid sample therealong from a sample contact region to a test site and a control site, and, ~~disposed~~ dried on said sorbent material upstream of said test site and said control site, a mobilizable conjugate comprising a specific binder for the ligand and a colored particulate material,

said test site comprising an immobilized first binding protein which binds specifically to the ligand, if the ligand is present in the liquid sample, and

said control site comprising an immobilized binder which binds said conjugate,

wherein said sample contact region, said test site, and said control site are in lateral flow fluid communication along said flow path, such that after a liquid sample suspected to contain the ligand is applied to said sample contact region,

said conjugate when mobilized moves along said flow path and binds to said immobilized binder of said control site to produce a color visible to the unaided eye indicative of a valid test result, and,

if the ligand is present in the liquid sample, a specific binding reaction product comprising the ligand and said conjugate binds to said immobilized first binding protein of said test site to produce a color visible to the unaided eye indicative of the presence of the ligand in the sample.

28. (Previously Presented) The test device of claim 27 further comprising a filter in said flow path upstream of said test site and control site.

29. (Previously Presented) The test device of claim 28 wherein said filter is defined by a portion of said sorbent material.

30. (Previously Presented) The test device of claim 27 wherein said control site is located downstream of said test site.

31. (Currently Amended) The test device of claim 27 wherein said ~~the~~ control site is a positive control site.

32. (Previously Presented) The test device of claim 27 wherein said first binding protein binds human chorionic gonadotropin.

33. (Previously Presented) The test device of claim 27 wherein said first binding protein binds human progesterone.

34. (Currently Amended) The test device of claim 27 wherein said conjugate ~~is disposed in dried form in said flow path and~~ is mobilized by liquid carrying the sample during use of said test device.

35. (Previously Presented) The test device of claim 34 wherein at least one of said first binding protein and said immobilized binder is a monoclonal antibody.

36. (Previously Presented) The test device of claim 27 wherein the colored particulate material is a metal sol particle.

37. (Previously Presented) The test device of claim 27 wherein said conjugate binds specifically to said immobilized binder.

38. (Currently Amended) A test device for determining the presence of a ligand in a liquid sample, the device comprising:

a test strip comprising a sorbent material which defines a flow path for transporting a liquid sample therealong from a sample contact region to a test site and a control site, and, ~~disposed~~ dried on said sorbent material upstream of said test site and said control site, a mobilizable conjugate comprising the ligand or a binding analog thereof and a colored particulate material,

said test site comprising an immobilized first binding protein which binds the ligand, if present in the liquid sample, and said conjugate, and

said control site comprising an immobilized binder which binds said conjugate,

wherein said sample contact region, said test site, and said control site are in lateral flow fluid communication through said flow path, such that after a liquid sample suspected to contain the ligand is applied to said sample contact region,

said conjugate when mobilized moves along said flow path and binds said immobilized binder of said control site to produce a color visible to the unaided eye indicative of a valid test result, and

the ligand, if present in the liquid sample, or said conjugate binds to said immobilized first binding protein of said test site, said conjugate when bound at said test site being visible to the unaided eye.

39. (Currently Amended) The test device of claim 38 wherein said conjugate ~~is disposed in dried form in said flow path and~~ is mobilized by liquid carrying the sample during use of said test device.

40. (Currently Amended) A test device for determining the presence of a ligand in a liquid sample, the device comprising:

a test strip comprising a sorbent material defining a flow path for transporting the liquid sample suspected to contain the ligand from a sample contact region to a test site and a control site;

a mobilizable conjugate dried on said sorbent material upstream of said test site and said control site, said conjugate comprising a first binding protein that specifically binds the ligand and ~~forms a conjugate with~~ a colored particulate material, so that when ligand is present in the liquid sample the conjugate forms a complex with the ligand;

a second binding protein that specifically binds the ligand for capturing the complex at the test site; and

a third binding protein for capturing the conjugate at the control site,

wherein the sample contact region, the test site, and the control site are in lateral flow communication along the flow path such that after liquid suspected to contain the ligand is applied to the sample contact region the conjugate when mobilized moves along the flow path and binds to the third binding protein of the control site to produce a color visible to the unaided eye indicative of a valid test result, and

wherein, if the ligand is present in the liquid sample, a specific binding reaction product comprising the ligand, the conjugate and the second binding protein accumulates in the test site to produce a color visible by the unaided eye indicative of the presence of the ligand in the sample.

41. (Previously Presented) The device of claim 40, wherein the first binding protein is an antibody.

42. (Previously Presented) The device of claim 40 or 41, wherein the first binding protein binds human chorionic gonadotropin.

43. (Previously Presented) The device of claim 40, wherein the second binding protein is an antibody.

44. (Previously Presented) The device of claim 40 or 43, wherein the second binding protein binds human chorionic gonadotropin.

45. (Previously Presented) The device of claim 40, wherein the second binding protein is an immobilized protein.

46. (Previously Presented) The device of claim 40, wherein the second binding protein comprises an antibody immobilized on a particle.

47. (Previously Presented) The device of claim 46, wherein the particle becomes entrapped in the test site.

48. (Currently Amended) An immunoassay device for determining the presence or concentration of a ligand in a liquid sample, the device comprising:

an elongate test strip comprising (i) a sorbent material which defines a lateral flow path for transporting by wicking or capillary action a liquid sample suspected to contain the ligand from a sample contact region to a test site and a control site, ~~together with~~ and (ii) dried on said sorbent material upstream of said test site and said control site a mobilizable conjugate comprising a colored particulate material bound to a binder for the ligand, the ligand or an analog of the ligand, ~~from a sample contact region~~ such that when the liquid sample is applied to the sample contact region the liquid sample mobilizes the conjugate and transports the conjugate to

~~a~~ said test site at which the ~~ligand,~~ the conjugate, or a complex of the ligand and conjugate aggregates to produce a color signal visible to the unaided eye, indicative of the presence, absence or concentration of the ligand and to

~~a~~ said control site at which the conjugate aggregates to produce a color signal visible to the unaided eye indicative of a valid test result.

49. (Cancelled)

50. (Cancelled)

51. (Previously Presented) The test device of claim 40 or 48, wherein the control site is located downstream of the test site.

52. (Previously Presented) The test device of claim 40 or 48, wherein the control site is a positive control.

53. (Previously Presented) The test device of claim 48, wherein the binder for the ligand is an antibody.

54. (Previously Presented) The test device of claim 53, wherein the antibody binds human chorionic gonadotropin.

55. (Previously Presented) The test device of claim 48, wherein the conjugate becomes entrapped in the test site.

56. (New) A test device comprising:

a test strip comprising a sorbent material defining a flow path extending from a sample contact region to a test site;

a mobilizable conjugate dried on the sorbent material upstream of the test site and comprising a first binder for a ligand and a colored particle bound thereto; and

a second binder for the ligand immobilized at the test site,

wherein the sample contact region and the test region are in lateral flow communication along the flow path, such that after a liquid sample suspected to contain the ligand is applied to the sample contact region, the conjugate, when mobilized by the liquid sample, moves along said flow path and, if ligand is present in the liquid sample, a specific binding reaction product comprising the ligand and the conjugate binds to the second binder of the test site to produce a color visible to the unaided eye indicative of the presence of the ligand in the liquid sample.

57. (New) The test device of claim 56 wherein the conjugate is transported along the flow path by liquid wicking or capillary action along the sorbent material.

58. (New) The test device of claim 56 wherein the second binder comprises an immobilized protein.

59. (New) The test device of claim 56 wherein the second binder comprises an immobilized antibody to the ligand.

60. (New) The test device of claim 56 wherein the first binder comprises a second antibody to the ligand.

61. (New) The test device of claim 56 wherein the first binder binds to human chorionic gonadotropin.

62. (New) The test device of claim 56 wherein the second binder binds to human chorionic gonadotropin.

63. (New) The test device of claim 56 wherein the first binder comprises a monoclonal antibody.

64. (New) The test device of claim 56 wherein the colored particle is a metal sol particle.

65. (New) The test device of claim 64 wherein the metal sol particle is colloidal gold.

66. (New) The test device of claim 56 further comprising a super sorbent material downstream of the test site, the test strip further defining a flow path to the super sorbent material.

67. (New) The test device of claim 56 wherein the test strip further comprises a control site.

68. (New) The test device of claim 67 wherein the control site is located downstream of the test site.

69. (New) A method of detecting a ligand in a liquid sample, the method comprising the steps of:

(a) providing a test device comprising

a test strip comprising a sorbent material defining a flow path extending from a sample contact region to a test site, wherein the sample contact region and the test region are in lateral flow communication along the flow path,

a mobilizable conjugate dried on the sorbent material upstream of the test site and comprising a first binder for a ligand and a colored particle bound thereto, and

a second binder for the ligand immobilized at the test site;

(b) applying a liquid sample to the sample contact region so that the sample and the conjugate, when mobilized, are transported to the test site by liquid wicking or capillary action along the flow path, and if ligand is present in the liquid sample, the ligand forms a complex with the conjugate; and

(c) observing visually the test result at the test site wherein an accumulation of colored particles at the test site produces a color indicative of the presence of the ligand in the liquid sample.

70. (New) The method of claim 67 wherein the second binder comprises an immobilized antibody to the ligand.

71. (New) The method of claim 67 wherein the second binder comprises a second antibody to the ligand.

72. (New) The method of claim 68 wherein the first binder binds to human chorionic gonadotropin.

73. (New) The method of claim 69 wherein the second binder binds to human chorionic gonadotropin.